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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,448	07/09/2001	Toni Ceccardi	CL001272	4232

25748 7590 09/30/2003

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EXAMINER

LI, RUIXIANG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/900,448	Applicant(s) CECCARDI ET AL.	
	Examiner Ruixiang Li	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 20, and 21, drawn to peptides, classified in class 530, subclass 350.
- II. Claim 3, drawn to an antibody, classified in class 530, subclass 387.9.
- III. Claims 4-6, 8-11, 22, and 23, drawn to nucleic acids, a vector, a host cell, and methods of producing peptides, classified in class 536, subclass 23.5 and class 435, subclass 320.1, 325, and 69.1.
- IV. Claim 7, drawn to a transgenic animal, classified in class 800, subclass 13.
- V. Claim 12, drawn to a method of detecting peptides, classified in class 435, subclass 7.1.
- VI. Claim 13, drawn to a method of detecting nucleic acids, classified in class 435, subclass 6.
- VII. Claim 14-15, drawn to a method of identifying peptide modulators, classified in class 435, subclass 7.1.
- VIII. Claims 16, drawn to a method of identifying peptide-binding agents, classified in class 435, subclass 7.1.
- IX. Claims 17 and 18, drawn to a method of disease treatment using peptide-binding agents, classified in class 514, subclass 2.
- X. Claim 19, drawn to a method of identifying a modulator of peptide expression, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other for the following reasons. Inventions I, II, III, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instant case, the different inventions are drawn to completely different products having completely different structures and biological functions which are not interchangeable and which require non-cohesive searches and considerations.
3. Inventions V, VI, VII, VIII, XI, and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instant case, the different inventions are drawn to completely different methods each having completely different method steps, using different compositions, and having completely different outcomes. First, the method of detecting peptides will not identify nucleic acids, peptide modulators, or peptide-binding compounds. Neither will it provide information regarding the method of treatment using peptide-binding agents or a method of identifying a modulator of peptide expression. Secondly, the method of detecting nucleic acids will not identify peptides, peptide modulators, peptide-binding compounds, or a modulator of peptide expression. It will not provide information regarding the method of treatment using peptide-binding agents. Third, The methods of identifying peptide modulators, peptide-binding compounds, or modulators of peptide expression will not provide information on the detection of peptides or nucleic acids and the method of

treatment using peptide-binding agents. Finally, the method of treatment will not provide information regarding the detection of peptides, nucleic acids, peptide modulators, or peptide-binding compounds. Thus, all the methods are exclusive.

4. Inventions I and V are related as product and process of use. The invention can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05 (h)). In the instant case, the peptide may be used in a materially different process such as to immunize with. For the same reason, Inventions I and VII, Inventions I and VIII are related but distinct inventions.
5. Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05 (h)). In the instant case, the nucleic acids may be used in a materially different process, such as the production of peptides.
6. Invention I is an independent invention from Inventions VI, IX, and X; Invention II is an independent invention from Inventions V-X; Invention III is an independent invention from Inventions V and VII-X; Invention IV is an independent invention from V-X. The different inventions are drawn to unrelated product and method inventions because the products cannot be used in the methods.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
8. Because these inventions are distinct for the reasons given above and the search required for a single group is not required for any other group, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published

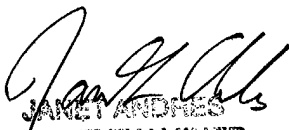
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in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG
89.

Any inquiry of a general nature or relating to the status of this application or
proceeding should be directed to the Group receptionist whose telephone number is
(703) 308-0196.

Ruixiang Li
Examiner
September 26, 2003


JANET ANDRES
PATENT EXAMINER